DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
504 SCOTT STREET
FORT DETRICK, MARYLAND 21702-5012

REPLY TO
ATTENTION OF:

MCMR-UMZ

2 MAR 2005

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: USAMRMC Regulatory Affairs/Sponsor's Representative to the FDA

1. Reference memorandum, USAMRMC, MCMR-ZA, 29 September 2004, subject: Realignment of the U.S. Army Medical Research and Materiel Command's (USAMRMC) Office of Regulatory Compliance and Quality (RCQ) Functions effective 1 October 2004.

2. On 29 September 2004, I directed the realignment of human subjects protection, quality, and regulatory affairs support in the Command by creating the Office of Research Protections and the USAMRMC Quality Management Office. As part of the 29 September memorandum, I directed that the USAMRMC mission for Regulatory Affairs policy and coordination would be transferred to the U.S. Army Medical Materiel Development Activity (USAMMDA). In that memorandum, I also identified Dr. Judy Pace-Templeton as Director of Regulatory Affairs.

3. The Regulatory Affairs leadership, policy and coordination functions of USAMRMC fall under the purview of USAMMDA. USAMMDA will develop dynamic partnerships with the Command's Office of Research Protection, Quality Management Office, MeRITS Office, other HQ elements, and the Regulatory Affairs and Quality Management units in the Command's Laboratories and Institutes to develop policies, guidance documents, training programs, and regulatory cost models to facilitate a common understanding and execution of Food and Drug Administration (FDA) regulated research. USAMMDA is the Command's interface with the FDA and maintains relationships with the Chemical Biological Medical Systems Program Management Office, the Defense Threat Reduction Agency, National Institute of Health, Health Affairs, and other partners to further the regulatory sufficiency of USAMRMC developed products.

4. As Commander of USAMRMC, I serve on behalf of The Surgeon General as sponsor of record with the FDA for Department of the Army regulated products. I have delegated the sponsor's representative responsibilities to the Commander, USAMMDA. As such, it is the responsibility of the sponsor's representative to ensure that the responsibilities of the sponsor are fulfilled. These responsibilities are executed either through USAMMDA or through further delegation of responsibilities to organizations in this Command or to external organizations, e.g., clinical research organizations. The Commander, USAMMDA, is responsible for delegating those responsibilities through appropriate clinical trial agreements, contracts, cooperative research and development agreements, or other correspondence.

5. The point of contact for this memorandum is Colonel Jerry Pierson, 301-619-7643 or email jerry.pierson@amedd.army.mil.

LESTER MARTINEZ-LOPEZ
Major General, MC
Commanding

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